REMARKS

Notice of Non-Compliant Amendment

Further to the Reply filed January 16, 2009, the instant Reply corrects the Status Identifier for claim 1 from "Original" to "Currently Amended".

The above amendments correspond to the amendments presented in the Reply filed January 9, 2009, except that claims 1 and 8 are identified by the proper status identifier It is noted that the Notice issued January 12, 2009, asserted that each claim was not provided with the proper status identifier, but failed to indicate which claim(s) was not in compliance.

The following remarks correspond to those presented in the Reply filed January 9, 2009.

Amendments

Claims 12-13 are cancelled. Claims 1-11 and 14-29 are amended to use language in accordance with conventional US practice and to delete superfluous language. For example, the reference to "pharmaceutically acceptable salts, derivatives, solvates and stereoisomers" is deleted from claim 2 as it is already recited in claim 1.

Medicament claims 9-10 are converted into pharmaceutical composition claims. Use claim 14 is converted into a method of treatment claim. See, e.g., page 41, lines 9-22. Use claims 15-29 are also converted into method of treatment claims.

New claims 30-38 are directed to further aspects of applicants' invention and are supported throughout the disclosure. See, e.g., page 16, lines 4-24, page 16, line 29 – page 17, line 2, and page 17, line 32 – page 19, line 26.

Election

In response to the Restriction Requirement, applicants hereby elect Group I, i.e., compounds wherein Y is phenyl or pyridyl, processes of making such compounds, and kits containing such compounds. Claims 1-11 and 30-38 read on the elected invention. In response to the Election of Species, applicants hereby elect the compound (5-Chloro-7-

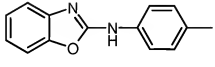
nitrobenzoxazol-2-yl)-[4-(pyridin-4-ylsulfanyl)phenyl]amine. See, e.g., Example 3 at page 61. Claims 1-5, 7-11, and 30-38 read on the elected species.

However, the Restriction Requirement is respectively traversed. In the Restriction it is asserted that the claims lack unity because under PCT Rule 13.2 they lack the same or corresponding special technical feature. Applicants respectfully disagree.

See section (d) of Annex B (Unity of Invention) of the Administrative Instruction under the PCT states that there are three particular situations for determining unity of invention under Rule 13.2. The principles for interpreting these three particular situations are discussed in sections (e), (f), and (g) of Annex B. Further, section (d) of Annex B makes it clear that the principles set forth in the discussion in sections (e), (f), and (g) are to be understood as an interpretation of the requirements under PCT Rule 13.2.

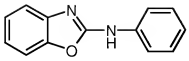
One of these three specific situations is "Markush" practice. The principles for interpreting unity of invention under Markush practice are discussed in section (f) of Annex B. Section (f) of Annex B states that the requirements for unity under PCT Rule 13.2 for a Markush grouping will be met if the alternatives of the grouping are of "a similar nature." Further, as indicated in section (f)(i), the alternatives will be regarded as fulfilling the criteria of being of a similar nature if the alternatives have a common property/activity and have a common significant structural element (i.e., a common chemical structure which occupies a large portion of their structure).

In the instant case, the compounds share the common activity of modulating signal transduction by kinases. In addition, the compounds exhibit a common significant structural element, namely:



Thus, the claimed Markush grouping satisfies the requirement of section (f) of Annex B and therefore meets the requirements for unity of invention under PCT Rule 13.2. Withdrawal of the Restriction as between Groups I and II is respectfully requested.

In the rejection, it is argued that the following structure is known in the art:



It is noted that this structure does not show all of the common structural features of the claimed compounds as it fails to show that the phenyl ring is para-substituted. The cited compound of US 2003/0225131 does not exhibit such a para-substituent.

Applicants also respectfully submit that 35 USC §121 does not permit restriction within a single claim as clearly indicated by the court in *In re Weber et al.,* 198 USPQ 328 (1978).

> As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.
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> It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular claim on that same basis. [*Weber* at 331-332]

The effect of restriction within a single claim is the same as a rejection. 35 USC §121 does not give the Commissioner authority to require that a single claim "be divided up and presented in several applications" and thus deny the Applicant the right to have that single claim considered on its merits.

As noted in MPEP §803.02, which describes the criteria for restriction practice relating to Markush-type claims, since the decisions in *In re Weber* and *In re Haas,* "it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." Thereafter, the MPEP cites *In re Harnish*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d (Bd. Pat. App. & Int. 1984). These two cases both deal with improper Markush rejections. Thus, in the case of Markush claims, refusal by the Office to examine that which the applicants regard as their

invention must be a refusal based on an improper Markush rejection. For the reasons discussed above, applicants Markush grouping is proper.

The Restriction Requirement is also traversed with respect to the Restriction between Groups I/II and Groups III/IV. The Restriction presents no rationale as to why the methods of using the compounds recited in the claims of Groups III/IV are being restricted from the compounds of Groups I/II.

Moreover, section (e)(i) of Annex B states that an independent product claim, an independent process claim specially adapted to manufacture the product, and an independent claim for use of the product is a permissible combination and will be construed as in compliance with the unity of invention requirement under PCT Rule 13.2. Thus, the Restriction presents no rationale as to why the claims directed to method of using compounds of Formula I should be restricted from the elected Group, i.e., the compounds of Formula I. Therefore, withdrawal of the Restriction as between Groups I/II and III/IV is respectfully requested.

Applicants note that Annex B was superseded by the PCT International Search and Preliminary Examination Guidelines issued in 2004. However, the ISPE guidelines on unity of invention are very similar to the prior Annex B. See sections 10.11-10.17 of the PCT International Search and Preliminary Examination Guidelines.

For the reasons stated above, withdrawal of the Restriction and examination of all pending claims is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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